UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 11, 2020

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bluebird bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-35966**	**13-3680878**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

60 Binney Street, Cambridge, MA	**02142**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (339) 499-9300

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	BLUE	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 11, 2020, bluebird bio, Inc. ("bluebird") announced its financial results for the three months ended March 31, 2020. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On May 11, 2020, bluebird issued a press release announcing that it has amended its existing co-promotion/co-development agreement with Bristol-Myers Squibb ("BMS") relating to idecabtagene vicleucel (ide-cel; bb2121), the companies’ lead investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy, which is currently in review with the FDA.

The full text of bluebird’s press release regarding this announcement is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on May 11, 2020 (regarding financial results).
99.2	Press release issued by bluebird bio, Inc. on May 11, 2020 (regarding BMS amendment).
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 11, 2020 bluebird bio, Inc.

By: /s/ Chip Baird
Chip Baird
Chief Financial Officer and Principal Financial Officer

Exhibit 99.1

bluebird bio Provides Operational and Business Update and Reports First Quarter 2020 Financial Results

- Alignment with FDA on an accelerated regulatory path for LentiGlobin for sickle cell disease based on HGB-206 study with targeted submission in 2H 2021 -
- Completed submission with Bristol Myers Squibb of Biologics License Application (BLA) for anti-BCMA CAR T cell therapy idecabtagene vicleucel (ide-cel, bb2121) to FDA -
- Amended BMS collaboration including $200 million monetization for ex-U.S. milestone and royalty revenue from idecabtagene vicleucel (ide-cel, bb2121) and bb21217 -
- Revised Operating Plan achieves cash savings of over $500 million through 2022 -
- Company extends cash runway into 2022 -
- Company to host conference call today, May 11, 2020 at 8:00AM ET -

CAMBRIDGE, Mass. – **May 11, 2020** – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the first quarter ended March 31, 2020 and provided an operational update.

“We remain grounded in our core values and priorities: our patients, our people, our community and our business,” said Nick Leschly, chief bluebird. “This quarter, we successfully submitted the ide-cel BLA with our partners at BMS and I am pleased to announce today that we have alignment with FDA on our clinical data package and filing path for LentiGlobin for sickle cell disease, which accelerates our planned base case filing timeline into 2021. Additionally, we are amending our co-promotion/co-development agreement with BMS to enable both companies to focus their efforts on efficient commercialization of ide-cel and generate non-dilutive capital for our business. Lastly, after a rigorous review of all operational plans to reflect COVID-19 uncertainties and recent program shifts, we have prioritized our core four programs to drive ide-cel launch and three filings in 2021 for CALD, TDT and SCD and continue to drive forward high potential pipeline assets. This prioritization effort and operational review has led to significant efficiencies and spend reduction across our company and will extend our cash runway into 2022. The fundamentals of our business remain sound and our newly revised operating plan enables us to execute on the 2022 vision while putting us on a path towards financial sustainability. Our team remains excited and committed to our mission with the belief we will emerge from a very tough period in history stronger than ever to deliver for patients. Thank you birds!”

SCD REGULATORY PATH

Today, bluebird bio announced general agreement with FDA that the clinical data package required to support a BLA submission for LentiGlobin™ for sickle cell disease (SCD) will be based on data from a portion of patients in the HGB-206 study Group C that have already been treated. The planned submission will be based on an analysis using complete resolution of severe vaso-occlusive events (VOEs) as the primary endpoint and at least 18 months of follow-up post drug product infusion. Globin response will be used as a key secondary endpoint. The company anticipates additional guidance from FDA regarding the commercial manufacturing process, including suspension lentiviral vector. The company is planning to seek an accelerated approval and expects to submit the U.S. Biologics Licensing Application (BLA) for sickle cell disease in the second half of 2021. bluebird bio plans to present updated data from the HGB-206 study at the European Hematology Association (EHA) Annual Meeting.

Additionally, to enhance its strategic, clinical and commercial manufacturing platform, bluebird bio has entered into expanded relationships with two subsidiaries of Hitachi Chemical Co., Ltd. (Hitachi Chemical Advanced Therapeutics Solutions and apceth Biopharma GmbH). These agreements will support late-stage and commercial drug product manufacturing of LentiGlobin for SCD in both the United States and Europe, expand commercial drug product manufacturing capacity for ZYNTEGLO® (betibeglogene autotemcel) in Europe, and expand clinical and commercial manufacturing capacity for Lenti-D for cerebral adrenoleukodystrophy (CALD) in Europe.

FINANCIAL AND BUSINESS UPDATES

IDE-CEL ROYALTY MONETIZATION AND BCMA RELATIONSHIP AMENDMENT

Today, bluebird bio announced in a separate press release that it has amended its existing co-promotion/co-development agreement with Bristol Myers Squibb (BMS) to enable the companies to focus their efforts on efficient commercialization of idecabtagene vicleucel (ide-cel; bb2121) in the U.S., the companies' lead investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy, currently in review with the FDA. The companies will continue to share equally profits and losses in the U.S. Under the terms of the amended agreement, BMS will buy out its obligations to pay bluebird bio future ex-U.S. milestone and royalty payments for ide-cel and bb21217, the companies' second BCMA-directed CAR T immunotherapy, for a one-time upfront payment of $200 million. bluebird bio is currently in the process of building out and qualifying its wholly-owned manufacturing facility in Durham, North Carolina for the production of lentiviral vector (LVV) to support the U.S. commercial market for ide-cel and for bluebird bio's pipeline. Over time, BMS will assume responsibility for manufacturing of LVV outside the U.S. In partnership with BMS, bluebird bio is planning to present updated ide-cel clinical data from the Phase 2 KarMMa study at the upcoming American Society of Clinical Oncology meeting.

REVISED BUSINESS PRIORITIES AND OPERATING PLAN

Given the ongoing impact of the COVID-19 global pandemic and recent shifts in regulatory timelines, bluebird bio has undertaken a comprehensive business review with the goal of ensuring the ability to achieve its 2022 vision with a path towards financial sustainability. Under the revised business priorities and operating plan, bluebird remains on track for potential regulatory approval and commercial launch for ZYNTEGLO, ide-cel, Lenti-D for CALD, and LentiGlobin for SCD by 2022.

Through this comprehensive business review, bluebird bio has prioritized key research and development programs and has made a number of changes to the future cost structure relative to the prior long-range plan, including:

- Reduced investment in selling, general and administrative expenses, including a deferred investment in building a U.S. commercial organization, reduced facilities and IT infrastructure, and other cost-reduction measures.
- Prioritized investment in R&D expenses, including an indefinite pause of the HGB-211 clinical study in SCD patients at high risk of stroke, adjustment to the timing of investment in ongoing clinical studies to reflect COVID-19 related delays in enrollment, reduction or elimination of investment in certain preclinical programs, and other cost-reduction measures.
- Nick Leschly, chief bluebird, will decline nearly 100% of his salary for the next 12 months. Similarly, additional members of the bluebird bio senior leadership team and all members of the

Company's Board of Directors will forgo 20% of their salaries or Board cash retainers for the next 12 months. All will receive a grant of restricted stock units equal to 80% of the value of the released cash compensation, which will vest over one year.

In total, these changes are expected to result in over $500 million of net cash savings through 2022 compared to the prior long-range plan. As a result, bluebird bio expects cash, cash equivalents, and marketable securities of $1.02 billion as of March 31, 2020, together with projected revenue generated under collaborative arrangements, projected sales of products and cash inflows associated with the amended agreements with BMS, to fund the revised operating plan into 2022. bluebird bio expects to continue to drive additional savings through rigorous prioritization and focus on expenses, real estate optimization, and exploration of additional sources of funding to further strengthen its financial position.

PREVIOUSLY DISCLOSED RECENT HIGHLIGHTS

- **IDE-CEL BIOLOGICS LICENSE APPLICATION (BLA) SUBMISSION –** On March 31, 2020, bluebird bio and BMS announced the submission of their BLA to the U.S. FDA for ide-cel, the companies' lead investigational BCMA-directed chimeric antigen receptor (CAR) T cell immunotherapy, for the treatment of adult patients with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody. The BLA submission includes results from pivotal KarMMa study evaluating ide-cel in a heavily pre-treated patient population with relapsed and refractory multiple myeloma.

- **COVID-19 IMPACT** – On March 26, 2020, bluebird bio provided an assessment of the impact of the COVID-19 pandemic and outlined steps the company has taken to ensure the safety of its patients and employees, while working to ensure the sustainability of its business operations as this unprecedented situation continues to evolve. Generally, the company expects the COVID-19 pandemic to shift the timing of enrollment and completion of clinical studies by at least three months and expects timing shifts to vary by clinical trial and by program.

UPCOMING ANTICIPATED MILESTONES

- **Regulatory**
  - Submission of a Marketing Authorization Application to the European Medicines Agency for Lenti-D in patients with cerebral adrenoleukodystrophy by the end of 2020.

- **Clinical**
  - Presentation of ide-cel clinical data from the KarMMa study at the American Society of Clinical Oncology meeting later this month, in partnership with Bristol-Myers Squibb.
  - Updated data presentation from the Northstar-2 (HGB-207) clinical study in patients with transfusion-dependent β-thalassemia (TDT) and non-β^0/β^0 genotypes at the 2020 Annual Congress of the European Hematology Association (EHA).
  - Updated data presentation from the Northstar-3 (HGB-212) clinical study in patients with TDT and a β^0/β^0 genotype or an IVS-I-110 mutation at the 2020 Annual Congress of EHA.
  - Updated data presentation from HGB-206 clinical study in patients with SCD at the 2020 Annual Congress of EHA.

- Presentation of ide-cel clinical data from the CRB-401 study in 2020, in partnership with Bristol-Myers Squibb.
- Updated data presentation from ALD-102 in patients with CALD by the end of 2020.

- **Commercial and Foundation Building**
  - ZYNTEGLO first commercial patients treated in Europe in the second half of 2020.
  - ZYNTEGLO access and reimbursement in additional EU countries established by the end of 2020.

FIRST QUARTER 2020 FINANCIAL RESULTS

- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2020 and December 31, 2019 were $1.02 billion and $1.24 billion, respectively. The decrease in cash, cash equivalents and marketable securities is primarily related to cash used in support of ordinary course operating and commercial-readiness activities.
- **Revenues:** Total revenues were $21.9 million for the three months ended March 31, 2020 compared to $12.5 million for the three months ended March 31, 2019. The increase was primarily attributable to an increase in ide-cel license and manufacturing service revenue under our agreement with BMS, as well as an increase in royalty revenue.
- **R&D Expenses:** Research and development expenses were $154.1 million for the three months ended March 31, 2020 compared to $122.6 million for the three months ended March 31, 2019. The increase was primarily driven by costs incurred to advance and expand the company's pipeline.
- **SG&A Expenses:** Selling, general and administrative expenses were $73.2 million for the three months ended March 31, 2020 compared to $60.3 million for the three months ended March 31, 2019. The increase was largely attributable to costs incurred to support the company's ongoing operations and growth of its pipeline as well as commercial-readiness activities.
- **Net Loss:** Net loss was $202.6 million for the three months ended March 31, 2020 compared to $164.4 million for the three months ended March 31, 2019.

CONFERENCE CALL DETAILS

bluebird bio will hold a conference call to discuss business updates and first quarter 2020 financial results on Monday, May 11 at 8:00AM ET.

Investors may listen to the call by dialing (844) 825-4408 from locations in the United States or +1 (315) 625-3227 from outside the United States. Please refer to conference ID number 335-5158.

About bluebird bio, Inc.
bluebird bio is pioneering gene therapy with purpose. From our Cambridge, Mass., headquarters, we're developing gene therapies for severe genetic diseases and cancer, with the goal that people facing potentially fatal conditions with limited treatment options can live their lives fully. Beyond our labs, we're working to positively disrupt the healthcare system to create access, transparency and education so that gene therapy can become available to all those who can benefit.

bluebird bio is a human company powered by human stories. We're putting our care and expertise to work across a spectrum of disorders including cerebral adrenoleukodystrophy, sickle cell disease, β-thalassemia and multiple myeloma, using three gene therapy technologies: gene addition, cell therapy and (megaTAL-enabled) gene editing.

bluebird bio has additional nests in Seattle, Wash.; Durham, N.C.; and Zug, Switzerland. For more information, visit bluebirdbio.com.

Follow bluebird bio on social media: @bluebirdbio, LinkedIn, Instagram and YouTube.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the company's financial condition, results of operations, as well as statements regarding the plans for regulatory submissions for the company's product candidates LentiGlobin for β-thalassemia, LentiGlobin for SCD, and Lenti-D, including anticipated endpoints to support regulatory submissions and timing expectations; the company's expectations and execution under its revised operating plan, including its cash runway; its expectations for commercialization efforts for ZYNTEGLO in Europe; and the company's expectations for the amended collaboration agreement with BMS; as well as the company's intentions regarding the timing for providing further updates on the development and commercialization of ZYNTEGLO and the company's product candidates. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risks that the COVID-19 pandemic and resulting economic conditions will have a greater impact on the company's operations and plans than anticipated, and that the company will not be able to realize the savings under the revised operating plan or successfully execute the revised operating plan; that our amended collaboration with BMS will not continue or be successful; that preliminary positive efficacy and safety results from our prior and ongoing clinical trials will not continue or be repeated in our ongoing or future clinical trials; the risk of cessation or delay of any of the ongoing or planned clinical studies and/or our development of our product candidates, including due to delays from the COVID-19 pandemic's impact on healthcare systems; the risk that the current or planned clinical trials of our product candidates will be insufficient to support regulatory submissions or marketing approval in the United States and European Union; the risk that regulatory authorities will require additional information regarding our product candidates, resulting in delay to our anticipated timelines for regulatory submissions, including our applications for marketing approval; the risk that we will encounter challenges in the commercial launch of ZYNTEGLO in the European Union, including in managing our complex supply chain for the delivery of drug product, in the adoption of value-based payment models, or in obtaining sufficient coverage or reimbursement for our products; and the risk that any one or more of our product candidates, will not be successfully developed, approved or commercialized. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the

Securities and Exchange Commission. All information in this press release is as of the date of the release, and bluebird bio undertakes no duty to update this information unless required by law.

Investors & Media

Investors:

Ingrid Goldberg, 410-960-5022
igoldberg@bluebirdbio.com

Elizabeth Pingpank, 617-914-8736
epingpank@bluebirdbio.com

Media:

Jenn Snyder, 617-448-0281
jsnyder@bluebirdbio.com

bluebird bio, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except per share data)

(unaudited)

	For the three months ended March 31,	
	2020	2019
Revenue:		
Service revenue	$ 16,833	$ 9,211
Collaborative arrangement revenue	2,302	1,966
Royalty revenue	2,728	1,294
Total revenues	21,863	12,471
Operating expenses:		
Research and development	154,123	122,640
Selling, general and administrative	73,248	60,279
Cost of royalty revenue	1,025	430
Change in fair value of contingent consideration	(3,108)	296
Total operating expenses	225,288	183,645
Loss from operations	(203,425)	(171,174)
Interest income, net	5,355	10,102
Other expense, net	(4,447)	(3,389)
Loss before income taxes	(202,517)	(164,461)
Income tax (expense) benefit	(94)	15
Net loss	$ (202,611)	$ (164,446)
Net loss per share - basic and diluted:	$ (3.64)	$ (2.99)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	55,590	54,957

bluebird bio, Inc.

Condensed Consolidated Balance Sheet Data

(in thousands, except per share data)

(unaudited)

	As of March 31, 2020	As of December 31, 2019
Cash, cash equivalents and marketable securities	$ 1,018,357	$ 1,237,966
Total assets	$ 1,529,104	$ 1,727,424
Total liabilities	$ 408,671	$ 442,431
Total stockholders' equity	$ 1,120,433	$ 1,284,993

Exhibit 99.2

bluebird bio Announces Amended BCMA CAR-T Collaboration Agreement

– Bristol Myers Squibb to buy out its ex-U.S. milestone and royalty obligations to bluebird bio for $200 million –
– Bristol Myers Squibb assumes responsibility for vector manufacturing in ex-US territories –
– bluebird to hold conference call and webcast today, May 11, 2020 at 8:00AM ET –

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"Under our amended collaboration, we and BMS are redoubling our commitment to ide-cel and optimizing the relationship as we work together to bring this critical treatment to patients in the commercial setting," said Joanne Smith-Farrell, PhD, Chief Business Officer and Oncology Franchise Leader, bluebird bio. "With bluebird exiting the passive participation as supplier outside the U.S., we and BMS are taking steps to ensure an efficient and robust supply chain for this program. This, together with the monetization of our ex-U.S. royalties and milestones will allow bluebird to continue to participate in co-developing and co-commercializing ide-cel within the U.S. and to refocus resources on our internal programs and pipeline."

"Our collaboration with bluebird has resulted in the first CAR T cell therapy submitted for regulatory approval to target the B-cell maturation antigen and for multiple myeloma," said Krishnan Viswanadhan, Pharm.D., Senior Vice President, Global Cell Therapy Franchise Lead for Bristol Myers Squibb. "This amended partnership allows Bristol Myers Squibb to leverage our global manufacturing capabilities and consolidate all responsibilities outside the United States."

The companies will continue to share equally profits and losses in the U.S. Under the terms of the amended agreement, BMS will buy out its obligations to pay bluebird bio future ex-U.S. milestone and royalty payments for ide-cel and bb21217, the companies' second BCMA-directed CAR T immunotherapy, for a one-time upfront payment of $200 million. bluebird bio is currently in the process of building out and qualifying its wholly-owned manufacturing facility in Durham, North Carolina for the production of lentiviral vector (LVV) to support the U.S. commercial market for ide-cel and for bluebird bio's pipeline. Over time, BMS will assume responsibility for manufacturing of LVV outside the U.S.

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Forward-Looking Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of pharmaceutical products. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on historical performance and current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, the possibility of unfavorable results from additional clinical trials of ide-cel, that ide-cel may not receive regulatory approval and, if approved, whether such product candidate for such indication described in this release will be commercially successful, and that the collaboration with Bristol Myers Squibb may not continue or be successful. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect bluebird bio's business, particularly those identified in the risk factors discussion in bluebird bio's Annual Report on Form 10-K for the year ended December 31, 2019, as updated by our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, bluebird bio undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise

Investors & Media

Investors:
Ingrid Goldberg, 410-960-5022
igoldberg@bluebirdbio.com
OR
Elizabeth Pingpank, 617-914-8736
epingpank@bluebirdbio.com

Media:
Jenn Snyder, 617-448-0281
jsnyder@bluebirdbio.com